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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,264	01/14/2004	Toshikazu Hirota	789_070 CON2	4900

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BURR & BROWN
PO BOX 7068
SYRACUSE, NY 13261-7068

EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	
MAIL DATE	**DELIVERY MODE**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,264	HIROTA ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed 28 June 2007 in which claims 1-4 and 13 were amended. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 February 2007 under 35 U.S.C. under 35 U.S.C. 102(e). The previous rejections under obviousness-type double patenting are maintained.

Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments and withdrawn rejections. New grounds for rejection are discussed.

The finality of the previous office action is withdrawn. This action is non-final.

Claims1-13 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inkjet deposition of nucleic acids, does not reasonably provide enablement for "capture material". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*,

858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to:

Breadth of the Claims

The claims are drawn to a biochip comprising spots of capture material, the biochip made using an ink jet process. The "capture material" is defined as a material that specifically reacts with a specimen to provide structural information about a structure within the specimen. The claimed "capture material" encompasses an enormous genus of materials organic and inorganic. The genus includes minerals which bind to and interaction with various cells; the genus includes cells, which bind to and interact with various receptors; the genus includes proteins of various and very large sizes, which bind to and interact with various binding partners; the genus includes tissues of various types, which bind to and interaction with various binding partners, the genus includes lipids, which bind to and interact with various binding partners; the genus includes steroids and hormones and drugs and etc. The list is capture materials encompassed by the claims is enormous.

The specification does not provide any limiting definition of the claimed capture material. The specification merely discusses and illustrates a DNA microarray (page 36). However, the specification does not teach, discuss, illustrate or exemplify any other of the capture materials encompassed by the claims.

Thus, while the specification is enabling for a DNA biochip, the specification is not enabling for the broadly claimed invention.

Nature of the Invention

The claims are drawn to a biochip comprising spots of capture material, the biochip made using an ink jet process. The nature of the invention is such that ink jet deposition of viscous solutions and/or large molecules presents problems. For example, Mutz et al teach using ink jet for production of peptide arrays suffers numerous drawbacks e.g. the heat to

which the peptide fluid is exposed during deposition degrades the peptides and the forcing required to eject the peptides can alter peptide structure, and the nozzles are subject to clogging which results in misdirected droplets; and the ink jet will not produce high-density arrays comparable to other techniques (¶ 5). Furthermore, Wenzel et al teach that the charge of the fluids being ejected will radically affect ink jet operation resulting in failure and/or clogging (Column 1, lines 12-18). Finally, Koto teaches that viscous fluids tend to clog ink jet nozzles (Column 1, lines 14-19). While the nature of ink jet deposition is well established, ejection of various fluids from the ink jet presents numerous problems. The instant specification does not address these problems or methods to overcome the problems so as to enable one of skill in the art to make and use the invention as claimed.

State of the Prior Art

The state of the biochip art is well established, as is the art of ink jet printing. As cited above, the prior art clearly addresses the numerous obstacles for printing various fluids using ink jet technology.

Neither the specification nor the prior art provide guidance on how to overcome the problems with ink jet deposition so as to enable one of skill in the art to make and use the invention as claimed.

Level of Predictability in the Art

The claims are drawn to a biochip comprising spots of capture material, the biochip made using an ink jet process. The level of predictability for producing the broadly claimed capture material is very low as evidenced by the problems associated with ink jet printing of various fluids. Given the enormous genus of capture material claimed and the problems of ink jet printing, the level of predictability for producing the claimed biochips is very low.

Existence of Working Examples

The specification does not provide working examples of the claimed biochips. The specification merely discusses and illustrates a DNA microarray (page 36). However, the specification does not teach, discuss, illustrate or exemplify any other of the capture materials encompassed by the claims. In a Declaration by the inventor filed 29 November 2006, results were provided to compare ink jet printing to pin head printing. The examples provided in the declaration do not define the composition of the capture material spotted so as to provide a working example of various members of the broadly claimed genus of capture materials. Therefore, the specification does not provide working examples of the claimed invention which would enable one of ordinary skill in the art to make and use the invention as claimed.

Quantity of Experimentation Required

The claims are drawn to a biochip comprising spots of capture material, the biochip made using an ink jet process. In view of the breadth of the claims being drawn to an enormous genus of capture materials; in view of the nature of the invention in which problems with ink jet printing various fluids and molecules are well documented; in view of the state of the prior art which discusses ink jet printing problems and suggests other methods of printing; in view of the of unpredictability in the art with regard to ink jet printing of various fluids; and in view of the lack of working examples of the broadly claimed invention, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

The skilled practitioner would first turn to the instant description for guidance in using the claimed invention. However, the description lacks clear evidence of how to use the claimed invention. As such, the skilled practitioner would turn to the prior art for such guidance, however, the prior art does not disclose a method of use. Finally, said practitioner would turn to trial and error experimentation to determine a relationship between the product and its method of use. Such efforts amount to undue experimentation.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,753,144. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a biochip having spots of differing spot size or spot concentration. The claim sets merely differ in that the patent claims define the spotted material as "DNA" (a species) while the instant claims define the material as capture material (a genus).

The courts have stated that a genus is obvious in view of the teaching of a species see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed capture material is obvious in view of the patent DNA.

6. The above rejection is reiterated from the previous office action. The rejection is maintained and made Final.

Conclusion

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
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